

REMARKS

1. Applicants appreciate the Examiner's continued attention to this application.
2. This response to the Office Action dated 7/15/2005 is additionally supported by the Declaration of Dennis G. Hooper, M.D., Ph.D., the original of which is submitted herewith.
3. In view of the Appeal Brief filed on 1/28/2003, the Office Action dated 7/15/2005 reopened prosecution of this application. In response, Applicant elects to file a reply under 37 CFR 1.111 to the non-final Office action.
4. Claims 49-64 are now pending in this application. In the interest of simplifying issues for the continued prosecution of this application, Applicant has canceled Claims 65-66 without prejudice.
5. Pending claims 49-64 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Youdim et al. in view of Warren (US Patent No. 4,435,384), Goust et al. (US Patent 4,001,080) and Lane et al. This rejection is respectfully traversed, and reconsideration is requested.
6. To make the four-way hypothetical combination of the cited references, the rejection relies on the statements in Warren that: "Transfer factor is obtained from the lymphocytes of a donor having no history of recurrent infection by herpes virus." (Col. 2, lines 35-37); and that the process in Warren includes the step: "1. Obtain a heparinized whole blood sample from a suitable donor." (Col. 2, lines 47-50).
7. Applicants have considered the cited references, including the hypothetical combination in the Office Action dated 7/15/2005 based on the cited statements in Warren.
8. The Warren patent teaches that transfer factor is obtained from any individual who has no history of a recurrent infection, specifically herpes virus. All cases cited in the Warren patent are patients with herpes simplex or condylomatous growth, not otherwise specified. Transfer factor was prepared by removing lymphocytes from a "suitable donor" that does not have a history of recurrent infection by herpes virus. Transfer factor was obtained from these lymphocytes that have been removed from any other patient other than

that one with the viral infection, i.e., an allogeneic donor, not an autologous donor. Thus, transfer factor as taught by Warren did not have any relationship or association with autologous donation.

9. It is clear that Warren's patent taught that transfer factor was to be used topically on patients with viral infections. Warren excluded taking cells from any patient with a history of such a viral infection. Thus, a routineer can not draw the conclusion that any source of lymphocytes can be used. The lymphocytes simply must come from any patient other than the patient being treated for such a skin infection.

10. Based on the accepted definition of "transfer factor" as being allogeneic and based on the concern for allogeneic donor issues in Warren (i.e., no history of herpes virus and concern for using "a suitable" donor), the proper understanding of the terms "donor" and "transfer factor" in Warren is solely in the context of allogeneic donation. Warren does not disclose or suggest autologous donation.

11. These remarks are supported by the declaration of Dennis G. Hooper, M.D., Ph.D., which is attached.

12. Based on the forgoing, the hypothetical combination of the four references made in the Office Action dated July 15, 2005 does not teach or suggest the invention as defined by Claims 49-64.

13. Reconsideration of the rejection of Claims 49-64 is respectfully requested. The pending claims are believed to be patentable and in condition for allowance, and such action is respectfully requested. If a telephone conference would expedite the prosecution of this application, the undersigned would appreciate the opportunity and can normally be reached at the telephone number below.

DATED: January 17, 2006

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I hereby certify that the enclosed paper or fee is being deposited with the U.S. Postal Service to "Addressee" Service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C.

Laurie

Moore

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Signature of Person Mailing Paper or Fee

Respectfully submitted,



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